**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

| | |
|---|---|
| MELISSA EBERT,<br><br>*Plaintiff*,<br><br>v.<br><br>C.R. BARD, INC., et al.,<br><br>*Defendants*. | CIVIL ACTION<br>NO. 12-01253 |

**PAPPERT, J.** **May 11, 2020**

**MEMORANDUM**

Melissa Ebert's doctor implanted in her a Bard G2 inferior vena cava filter—a prescription medical device—to prevent pulmonary embolism. One of the filter's struts eventually fractured and migrated to Ebert's pulmonary artery. Both the filter and fractured strut were later removed from Ebert's body without complication. Ebert filed this lawsuit against Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. (collectively as "Bard") alleging claims of negligence, breach of express warranty, negligent misrepresentation and strict liability. Bard filed a Motion for Summary Judgment on all of Ebert's claims. After thoroughly reviewing the record and hearing oral argument, the Court grants the Motion in its entirety for the reasons that follow.

I

A

Ebert was diagnosed with a deep vein thrombosis on January 7, 2008. (Defs.' Statement of Undisputed Facts ("Defs.' SOF") ¶ 6, ECF No. 132-2.) Deep vein thromboses are blood clots that can travel to the lungs, causing a pulmonary embolism.

(*Id.* ¶ 1.) Pulmonary emboli, in turn, can cause chest pain, shortness of breath and death. (*Id.* ¶ 2.) Ebert's physician, Dr. Michael Ringold, treated her initially with a device called a Celect inferior vena cava (IVC) filter, which was manufactured by Cook Medical. (*Id.* ¶ 7.) IVC filters are designed to catch blood clots and prevent them from reaching the heart and lungs. *See* (G2 Information for Use ("G2 IFU") 4, Ex. C, ECF No. 132-5).[1] Shortly after Dr. Ringold implanted the Celect filter, several of its struts penetrated the wall of Ebert's IVC and one strut touched her aorta, causing inflammation. (Defs.' SOF ¶ 8.) As a result, on January 29, 2008, Dr. Ringold removed Ebert's Celect filter and replaced it with a Bard G2 filter—the device at issue in this case. (*Id.* ¶ 9.)

Before Dr. Ringold implanted the G2 filter in Ebert, he showed her a brochure published by Bard so that she could see what the filter looked like. (Ebert Dep. 220:5–24, Ex. V, ECF No. 138-22; Ex. I, ECF No. 132-11.) The G2 filter consists of two tiers of struts that make up its arms and legs; once deployed inside the body, the arms and legs open and anchor to the walls of the IVC. *See* (G2 IFU 4–5). The G2 filter is a retrievable filter, meaning it can be removed percutaneously after implantation. The device, however, was intended to be a permanent solution for Ebert's risk of deep vein thrombosis and pulmonary emboli. (G2 IFU 4; Ringold Dep. 30:23–31:15, Ex. A, ECF No. 133-1; Ex. A, ECF No. 138-1.)

Approximately three years later on March 22, 2011, Dr. Ringold removed Ebert's G2 filter and during that procedure, he discovered that one of the filter's struts had fractured and believed that it had endothelialized in the side of her IVC, meaning

[1] Citations to the G2's Information for Use refer to the ECF pagination rather than to the document's internal pagination.

tissue had grown around the strut holding it in place. (Defs.' SOF ¶¶ 10–11; Ringold Dep. 47:9–25.) After weighing the risks of removing the fractured strut against the benefits of leaving it in place, Dr. Ringold left the strut inside of Ebert. (Ringold Dep. 47:9–25.)

On October 11, 2011, Ebert presented to the emergency room with severe lower back pain. (Defs.' SOF ¶ 13.) She believed that the G2 filter's strut had migrated from her IVC to somewhere near her spine. (*Id.*) A CT scan of Ebert's chest revealed that the fractured strut had moved to a branch of her pulmonary artery in the left lower lobe of her lung. (*Id.* ¶ 14.) At that point, Ebert underwent an endovascular procedure to remove the fractured strut. (*Id.* ¶ 15.) In 2012, a cardiologist evaluated Ebert's heart and lungs and concluded they were functioning normally. (*Id.* ¶ 16.) An echocardiogram taken that year of Ebert's heart also revealed no physical damage. (*Id.* ¶¶ 17–18.)

B

Bard first began distributing IVC filters in 1992, when it marketed and sold the Simon Nitinol Filter (SNF)—a permanent device manufactured by Nitinol Medical Technologies. (Nitinol Medical Technologies Acquisition Proposal 3, Ex. C, ECF No. 145-2.)[2] After acquiring Nitinol Medical Technologies' IVC filter line, Bard developed its own modified IVC filter called the Recovery. *See generally* (Vena Cava Filter Overview (Glen Falls), Ex. D, EXF No. 145-3). The FDA initially approved the Recovery filter as a permanent device in November of 2002, followed by its approval as a retrievable device in July of 2003. *See* (Nov. 27, 2002 FDA Letter, Ex. E, ECF No.

[2] Citations to the Nitinol Medical Technologies Acquisition Proposal refer to the ECF pagination rather than to the document's internal pagination.

145-4; July 25, 2003 FDA Letter, Ex. F, ECF No. 145-5). In August of 2005, Bard obtained FDA approval to market the G2 filter as a substantially equivalent device to its predicate filter, the Recovery. *See* (Aug. 29, 2005 FDA Letter, Ex. B, ECF No. 145-1).

All IVC filters—both Bard and non-Bard devices alike—carry well-known risks, including the possibility of fracture, migration and perforation. *See generally* (Grassi, *Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism* ("IVC Article"), Ex. B, ECF No. 132-4; Defs.' SOF ¶¶ 20–21.) A 2003 article, for example, reported that the rate of filter fracture in all IVC filters ranged from two to ten percent. (IVC Article 4.)

The G2 filter's Information for Use (IFU) warned generally about these risks. For example, the IFU's "Warnings" and "Potential Complications" sections both cautioned that "filter fracture is a known complication" of IVC filters, and that "[t]here have been reports of embolization of vena cava filter fragments resulting in retrieval of the filter fragments using endovascular and/or surgical techniques." (G2 IFU 4–5.) It also stated that "[m]ost cases of filter fracture, however, have been reported without any adverse clinical sequelae." (*Id.*)

At the time Dr. Ringold implanted the G2 filter in Ebert, he was aware of the general risks associated with IVC filters. He first learned of the risks of penetration, fracture, embolization and migration as early as the 1990s during his residency and fellowship. (Ringold Dep. 15:20–16:12.) Dr. Ringold, however, testified that he never read the G2 filter's IFU in its entirety, and he could not recall whether he read the IFU at any point prior to implanting the device in Ebert. (*Id.* 23:25–24:7; Defs.' SOF ¶ 35.)

C

Ebert asserts the following causes of action: (1) negligence—design defect; (2) negligence—failure to warn; (3) breach of express warranty and implied warranty of merchantability; (4) negligent misrepresentation; and (5) strict liability. (Compl., ECF No. 1.) She seeks both compensatory and punitive damages. (*Id.*) After Ebert filed her Complaint, the Judicial Panel on Multidistrict Litigation transferred her case to the United States District Court for the District of Arizona for consolidated pretrial proceedings. (ECF No. 117.) The case has since returned to the Eastern District of Pennsylvania (ECF No. 118), and Bard filed a Motion for Summary Judgment on all of Ebert's claims. (ECF No. 132.) In her Response, Ebert informed the Court that she no longer intends to pursue the breach of implied warranty of merchantability claim but otherwise opposes the Motion in full. (ECF Nos. 133 & 138.) The Court heard oral argument on April 27, 2020. (ECF No. 154.)

II

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A dispute is genuine if the evidence is such that a reasonable factfinder could return a verdict for the nonmoving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Summary judgment is granted where there is insufficient record evidence for a reasonable factfinder to find for the plaintiff. *Id.* at 252. "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Id.*

When ruling on a motion for summary judgment, the court may rely only on admissible evidence. *See, e.g.*, *Blackburn v. United Parcel Serv., Inc.*, 179 F.3d 81, 94 (3d Cir. 1999). A court must view the facts and draw all reasonable inferences in favor of the nonmoving party. *See In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 357 (3d Cir. 2004). "An inference based upon a speculation or conjecture does not create a material factual dispute sufficient to defeat entry of summary judgment." *Robertson v. Allied Signal, Inc.*, 914 F.2d 360, 382 n.12 (3d Cir. 1990).

III

A

Count I of Ebert's Complaint alleges negligence against Bard, and she bases her claim upon two theories of liability: design defect and failure to warn. "To prevail in a negligence action, a plaintiff 'must show that the defendant had a duty to conform to a certain standard of conduct, that the defendant breached that duty, that such breach caused the injury in question, and actual loss or damage.'" *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 61 (3d Cir. 2009) (quoting *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003)). The Court addresses the negligent design defect and negligent failure to warn theories in turn.

1

Bard argues Ebert presents no evidence showing that the G2 filter was too harmful to be used by anyone. (Defs.' Mot. Summ. J. ("Defs.' Mot.") 7–9, ECF No. 132-1; Apr. 27, 2020 Hr'g Tr. 12:19–13:6, ECF No. 154.) Ebert, in turn, contends that she has presented enough facts, including evidence of a reasonable alternative design, to

send the negligent design defect claim to a jury. (Pl.'s Am. Resp. ("Pl.'s Resp.") 7–13, ECF No. 138.)

In *Lance v. Wyeth*, the Pennsylvania Supreme Court held for the first time that negligent design defect claims are cognizable in the prescription drug context. 85 A.3d 434 (Pa. 2014); *see Kramme v. Zimmer, Inc.*, 2015 WL 4509021, at *6 (M.D. Pa. July 24, 2015) (applying *Lance* to prescription medical devices). Both parties agree that *Lance* governs Ebert's negligent design defect claim. The parties dispute, however, the duty of care *Lance* established for such claims.

According to Bard, *Lance* requires medical device manufacturers to abide by the following narrow duty of care: "Under Pennsylvania law, pharmaceutical companies violate their duty of care if they introduce a drug into the marketplace, or continue a previous tender, with actual or constructive knowledge that the drug is too harmful to be used by anyone." *Lance*, 85 A.3d at 461. Ebert contends that the duty is far broader and relies on the following language from *Lance* to support her argument: "[T]he law of negligence establishes a duty, on the part of manufacturers, which can be viewed on a continuum from the requirements of: a warning of dangers, through a stronger warning if justified by the known risks, through non-marketing or discontinuance of marketing when it becomes or should become known that the product should not be used in light of its relative risks." *Id.* at 459–60.

The Court agrees with Bard's reading of *Lance*, which holds that a prescription medical device manufacturer violates its duty of care—as it applies to negligent design defect claims—when it "tender[s] into the market a drug which it knows or should know is so dangerous that it should not be taken by anyone." *Id.* at 458; 461; *see Stevens v.*

*C.R. Bard, Inc.*, 2018 WL 692097, at *3 (W.D. Pa. Feb. 2, 2018) (explaining that *Lance* recognized negligent design defect claims against prescription drug manufacturers, and that companies "tendering into the market a drug which it knows or should know is so dangerous that it should not be taken by anyone can be said to have violated its duty" (quoting *Lance*, 85 A.3d at 458)).[3]

Ebert is admittedly not alone in her reliance on *Lance's* "continuum" language. *See, e.g.*, *Crockett v. Luitpold Pharms. Inc.*, 2020 WL 433367, at *11 (E.D. Pa. Jan. 28, 2020) (limiting *Lance* to its facts and declining "to apply such a burdensome standard"); *Kramme*, 2015 WL 4509021, at *6 ("We do not believe that the Pennsylvania Supreme Court intended to limit negligence claims to only those products too dangerous to be taken by anyone."). The Court does not dispute that the duty of care for negligence claims exists on a spectrum. *Lance*'s "continuum" language, however, is dicta explaining the range of duties of care applicable to negligence claims *generally*. (Apr. 27, 2020 Hr'g Tr. 12:5–18.) The first two duties that *Lance* lists—to "warn[ ] of dangers" and to provide "a stronger warning if justified by the known risks"—apply to negligence claims brought under a failure to warn theory.[4] *See Lance*, 85 A.3d at 459–60. The third identified duty—"the non-marketing or discontinuance of marketing when it becomes or should become known that the product simply should not be used in

[3] When deciding *Lance,* the Pennsylvania Supreme Court was not presented with the question of whether to adopt the Restatement Third's approach to negligent design defect claims involving prescription drugs. *Lance*, 85 A.3d at 461 n.37. Nonetheless, the court noted that "Pennsylvania law at the very least overlaps or intersects with the Restatement Third principle that a manufacturer marketing a prescription drug [or medical device] which it knows or should know is too dangerous for anyone to use violates the standard of due care and may be liable under fault-based tort law." *Id.* (citing Restatement (Third) of Torts: Prod. Liab. § 6(c)).

[4] Whether Bard violated its duty to warn of the risks associated with the G2 filter is discussed *infra* in Section III.B.

light of its relative risks"—in turn, relates to claims brought under theories of negligent design defect or negligent marketing. *Id.*

2

There is no record evidence that Bard placed the G2 filter into the market "with actual or constructive knowledge that the [device was] too harmful to be used by anyone." *Lance*, 85 A.3d at 461. As Bard points out, and Ebert does not contest, no regulatory body or medical society has ever indicated that the G2 filter should not be used for any class of patients, or is otherwise unsafe for use.[5] (Defs.' SOF ¶¶ 38–39.) Ebert seeks to establish a genuine issue of fact by pointing to Dr. Ringold's deposition testimony, where he explained that his medical practice stopped using Bard's filters after he "experienced some complications" with their devices, including Ebert's filter fracture. (Ringold Dep. 68:11–69:23; 83:16–85:8.) According to Dr. Ringold, he and his partners stopped using the G2 filter after two patients (out of several hundred) experienced filter fracture, and a subsequent search in the FDA's MAUDE database revealed other similar adverse event reports. (*Id.* at 83:16–85:24.)

Dr. Ringold, however, testified based on his own personal experiences. (*Id.* at 84:16–19.) Ebert points to no record evidence—from Dr. Ringold's deposition, her

---

[5] At oral argument, Bard also made much of the fact that an internal Bard email initially reported that the G2 filter had a failure rate of 0.06%. (Nov. 2005 Bard Email, Ex. M, ECF No. 145-19.) Counsel for Bard stated that "because 99.94 percent of G2 filters have no reported rate of fracturing. . . no reasonable jury could be able to infer that [the] product is defective." (Apr. 27, 2020 Hr'g Tr. 113:12–17.)

After the Court held oral argument, Ebert sought leave to file a Sur-Reply, evidently seeking to rebut this seemingly low reported failure rate. (ECF No. 156.) The Sur-Reply included additional studies regarding the failure rates for IVC filters, including G2 filters specifically. One study found a 12% fracture rate in G2 filters. *See* (Nicholson Article 2, Ex. Y, ECF No. 157-3). Another study reported the G2 filter having a fracture rate of 31%. *See* (Angel Article 7, Ex. X, ECF No. 157-2). Both of these studies were published years after Dr. Ringold implanted the G2 filter in Ebert. However, neither a 0.06% or a 31% failure rate is dispositive to the outcome of this or any other of Ebert's claims.

expert witnesses' reports or otherwise—indicating that that "no reasonable physician would prescribe" or implant the G2 filter, or consider it to be too harmful to be used by *any* class of patients. *Lance*, 85 A.3d at 457 n.33; *see id.* (recognizing the difficulty of proving a negligent design defect claim where the "prescription drug maintained its FDA approval, it remained on the market, and U.S. doctors continued to prescribe it"). Indeed, no regulatory body has ever said the G2 should not be used by any class of patients or is otherwise unsafe, something Ebert does not dispute. (Defs.' SOF ¶ 38.)

3

Ebert—both in her Response and at oral argument—contends alternatively that she can establish Bard breached its duty of care by presenting evidence of a safer alternative design that could have been adopted. (Pl.'s Resp. 8–13; Apr. 27, 2020 Hr'g Tr. 83:14–20.) In particular, Ebert points to Dr. McMeeking and Dr. Ritchie's expert reports in which the doctors opine that an alternative design was both technologically and economically feasible at the time Bard manufactured the G2 filter. (Pl.'s Resp. 8–13.) McMeeking's proposed alternative design, for example, would utilize a "chamfer or rounding on the otherwise sharp edges" and a "shorter sheath with a longer length of arms and legs outside the sheath" to reduce the strain put on the filter. (McMeeking Report 26, Ex. S, ECF No. 133-19.) The wires on the alternative design would also be electropolished as a way to improve fatigue resistance, thereby reducing the risk of fracture. *See* (*id.*)

"[P]laintiffs frequently attempt to demonstrate the availability of a safer alternative design to establish a product defect." *Lance*, 85 A.3d at 458 n.36. Yet in the context of prescription drugs and medical devices, the court in *Lance* acknowledged that

the alternative design approach "is not an easy fit measured against conventional design theory . . . on account of speculativeness concerning whether FDA approval could ever be had for a new 'design.'" *Id.* at 458–59 (citations omitted). Moreover, even assuming the McMeeking Report creates a genuine issue of fact as to whether a reasonable alternative design was feasible, Ebert nonetheless fails to present evidence that the G2 filter was "too harmful to be used by anyone." *Id.* at 461.

B

Ebert also brings her negligence claim under a failure to warn theory. Bard argues that summary judgment should be granted in its favor for two independent reasons. *See* (Defs.' Mot. 9–12). First, that the warnings Bard provided about the G2 filter were adequate as a matter of law. (*Id.* at 9–11.) And second, even if the Court found the warnings to be inadequate, the claim nevertheless fails because Ebert cannot prove proximate causation. (*Id.* at 11–12.) In response, Ebert argues that Bard's warnings were inadequate because they did not include comparative failure rates, and had Dr. Ringold known of the comparative risks, he would have used a different filter. *See* (Pl.'s Resp. 13–18).

1

"In the duty to warn context, assuming that plaintiffs have established both duty and a failure to warn, plaintiffs must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996) (quoting *Mazur v. Merck & Co. Inc.*, 742 F. Supp. 239, 262 (E.D. Pa. 1990)). Because the G2 filter is a prescription

medical device, the learned intermediary doctrine applies to Ebert's claim. *See Daniel v. Wyeth Pharm., Inc.*, 15 A.3d 909, 924 (Pa. Super. Ct. 2011). Under this doctrine, the manufacturer's duty to warn "must be directed to the physician, not the consumer." *Id.* (quoting *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. Ct. 1990)). "Thus, in an action against a drug [or device] manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate." *Id.* (quoting *Taurino*, 579 A.2d at 927).

Under Pennsylvania law, the determination of whether a warning is adequate is initially a question of law. *See Mazur v. Merck & Co., Inc.,* 964 F.2d 1348, 1366 (3d Cir. 1992) (citing *Mackowick v. Westinghouse Elec. Corp.*, 575 A.2d 100, 102 (Pa. 1990)). "For a warning to be adequate as a matter of law . . . it must: (1) accurately and unambiguously convey the scope and nature of the risk, and (2) state the risk with sufficient specificity." *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 462 (W.D. Pa. 2019) (applying Pennsylvania law). "[W]here fact questions exist (e.g., regarding the sufficiency of the warning for a particular risk identified in the label and whether the warning was diluted by marketing representations), the question of adequacy is one for the jury." *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 817 F. Supp. 2d 535, 545–46 (E.D. Pa. 2011) (citing *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971)). The adequacy of a warning is determined based on what the manufacturer knew, or should have known, about a given risk at the time the patient was prescribed the medical device, and whether the label warned of that risk. *Id.* at 545–46. Expert medical testimony is generally required "to determine whether the drug manufacturer's warning to the medical community is adequate." *Demmler*, 671 A.2d at 1154.

2

Neither party disputes that Bard provided general warnings, including the risk of filter fracture, in the G2 filter's IFU. The "Warnings" section of the IFU cautioned that "[f]ilter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequalae." (G2 IFU 4.) An identical warning was also included in the "Potential Complications" section. (*Id.* at 5.) That section stated in bold print that "[a]ll of the above complications have been associated with serious adverse events such as medical intervention and/or death." (*Id.*) Notwithstanding the fact that the IFU warned of the specific complication that Ebert experienced—*i.e.*, filter fracture—she contends that the warnings were still inadequate; specifically, she argues that Bard breached its duty to warn by failing to provide comparative failure rates between the G2 filter and other Bard and non-Bard devices. (Pl.'s Resp. 14–15.)

Again, Dr. Ringold was independently aware of the general risks associated with IVC filters, including filter fracture. (Ringold Dep. 15:20–16:12.) Dr. Ringold testified, however, that he never read the G2 filter's IFU in its entirety and could not recall if he ever read the IFU prior to implanting Ebert with the G2 filter. (Defs.' SOF ¶ 35; Ringold Dep.23:25–24:7.) Ebert points out, however, that Dr. Ringold testified at his deposition that he "probably would not use the [G2] filter," had he known there was a significant risk of fracture. *See* (Ringold Dep. 71:2–10). Yet this testimony does not

negate the underlying, undisputed fact that he did not entirely read the G2 filter's IFU in the first place. (Defs.' SOF ¶ 35.)

Ebert relies primarily on *Schrecengost v. Coloplast Corp.* in arguing that there is a triable issue of fact for the proximate cause element of her claim. 425 F. Supp. 3d 448 (W.D. Pa. 2019); *see* (Apr. 27, 2020 Hr'g Tr. 88:5–90:2). Schrecengost asserted, among others, a negligent failure to warn claim, after she experienced complications from a surgical mesh implant. *Id.* at 452. The court denied the defendant's motion for summary judgment on that claim because there were genuine issues of fact about whether the plaintiff's doctor reviewed the surgical mesh's IFU before her surgery. *Id.* at 462–63. The defendants asserted that the physician had no recollection of reading or referring to the IFU prior to performing the procedure, whereas the plaintiff argued that her doctor reviewed the IFU prior to her surgery and relied on its warnings. *Id.* at 453.

Here, however, there is no room for such disagreement; Dr. Ringold did not read the G2 filter's IFU in its entirety, nor could he recall whether he read it before implanting the filter in Ebert. (Defs.' SOF ¶ 35; Ringold Dep. 23:25–24:7.) In fact, Ebert's counsel admitted during oral argument that if Dr. Ringold was called as a witness at trial, he could not testify that he "relied on the IFU in making [his] decision to use the G2 . . . over another type of filter." (Apr. 27, 2020 Hr'g Tr. 75:22–76:3.) Thus, even assuming that the warnings were inadequate, more detailed warnings, such as comparative failure rates, would have made no difference in Dr. Ringold's decision to implant the G2 filter in Ebert. *See, e.g.*, *Kline v. Zimmer Holdings, Inc.*, 2015 WL 4077495, at *25 (W.D. Pa. July 6, 2015) (explaining doctor's failure to read the

warnings in the package insert of a hip replacement device was fatal to plaintiff's negligent failure to warn claim). Because Ebert offers no evidence that Dr. Ringold read the IFU in its entirety or relied on it prior to implanting the G2 filter, she cannot prove that an inadequate warning proximately caused her injury.[6]

C

Count II of Ebert's Complaint alleges breach of express warranty.[7] She claims that the following statement in the G2 filter's IFU created such a warranty: "Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae." (Pl.'s Resp. 18 (quoting G2 IFU 4).) Bard contends it is entitled to summary judgment on this claim because "no such affirmations of fact or promises exist between Bard and Plaintiff," considering Ebert never talked to anyone at Bard and she never received any information from the manufacturer directly. (Defs.' Mot. 12–13; Defs.' SOF ¶ 36.)

1

[6] Ebert also contends that Bard's sales representatives should have warned Dr. Ringold of the comparative failures rates between G2 filters and other Bard and non-Bard filters. (Pl.'s Resp. 14–18; Apr. 27, 2020 Hr'g Tr. 77:22–78:4; 91:4–8.) The Court, however, is aware of no legal authority (and Ebert has provided none) that a medical device manufacturer's duty to warn extends beyond that which it must include in its products' IFUs and other written publications. *See* (Apr. 27, 2020 Hr'g Tr. 67:9–68:9). Nor has Ebert pointed to any record evidence demonstrating that it is the custom of the medical device industry to convey such risks through sales representatives. As such, the Court limits its analysis of Ebert's negligent failure to warn claim to those warnings published in the G2 filter's IFU.

[7] Count II also included a claim for breach of implied warranty of merchantability, but Ebert withdrew that claim. (Pl.'s Resp. 18.)

To prevail on a breach of express warranty claim, a plaintiff must establish that a breach of warranty occurred and that the breach was the proximate cause of the specific damages sustained. *Samuel-Bassett v. Kia Motors Am. Inc.*, 34 A.3d 1, 35 (Pa. 2011) (citing *Price v. Chevrolet Motor Div.*, 765 A.2d 800, 809 (Pa. Super. Ct. 2000)). Under Pennsylvania law, an express warranty is created by "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." 13 Pa. Con. Stat. § 2313(a)(1). A plaintiff satisfies the "basis of the bargain" requirement by "proving that she read, heard, saw or knew of the advertisement containing the affirmation of fact or promise." *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 752 & n.10 (W.D. Pa. 2004) (quoting *Cipollone v. Liggett Grp., Inc.*, 893 F.2d 541, 567 (3d Cir. 1990), *rev'd on other grounds*, 505 U.S. 503 (1992)).

There is no evidence in the record that Ebert read, heard, saw or knew of any statements that Bard published in the G2 filter's IFU—the document which forms the very basis of her breach of express warranty claim. Indeed, she does not dispute the fact that she never "talked to, received any information from, or relied on any information supplied by Bard before treatment with the G2 filter." (Defs.' SOF ¶¶ 36–37; Ebert Dep. 265:19–266:2.) Immediately before Dr. Ringold implanted the G2 filter in her, however, Ebert recalled him showing her a Bard brochure for the sole purpose of looking at a picture of the G2 filter. (Ebert Dep. 220:5–24.) That was the extent of her review; she testified that she "wasn't given a brochure" but just looked at an image of the filter while "gowned up and ready to go under the knife." (*Id.* at 220:9–24.) Nothing in the record shows that any affirmation of fact or promise in the IFU or in the

brochure concerning fracture rates or product safety became part of the "basis of the bargain." *See, e.g.*, *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 752–53 (E.D. Pa. 2007) (granting summary judgment on breach of express warranty claim where plaintiff offered no evidence that she relied on any express statements from the defendant medical device company).

2

Notwithstanding the fact that Ebert never received any affirmations of fact or promises from Bard directly, she argues that her breach of express warranty claim should proceed to trial because she *indirectly* relied on the warranty, "as explained by Dr. Ringold through the informed consent process." (Pl.'s Resp. 19.) Several problems, both legal and factual, undermine this argument.

First, Ebert's dependence on *Rosci v. AcroMed, Inc.*, 669 A.2d 959 (Pa. Super. Ct. 1995), to support her indirect reliance theory is misplaced. *See* (Pl.'s Rep. 19). In *Rosci*, a manufacturer of bone plates and screws expressly warranted that the medical devices would conform to the descriptions on their package inserts. *Rosci*, 669 A.2d at 967. The patient brought a breach of express warranty claim, but the trial court granted summary judgment to the manufacturer after concluding that the learned intermediary doctrine precluded the suit. *Id.* at 968. The court in *Rosci* reversed the trial court, holding that the learned intermediary doctrine does not apply to breach of express warranty claims, because such claims are "unrelated to the issue of the warnings given to the prescribing physician and instead [are] based solely upon the express affirmation of fact made by the manufacturer." *Id.* at 969. *Rosci* further explained that a medical device manufacturer "should not be heard to defend its failure to conform to those

representations solely because the literature in which they are contained was directed to the prescribing physician rather than to the patient," who was the intended recipient of the medical device. *Id.*

Ebert seeks to extend *Rosci*'s reach by claiming that any representation directed at a physician forms the basis of a breach of warranty claim if the physician later communicates that representation to the patient. *See* (Pl.'s Resp. 19). *Rosci*'s holding, however, is far narrower; it held that the learned intermediary doctrine does not preclude breach of express warranty claims against medical device manufacturers. *Id.* at 968. Nothing in *Rosci* alters the requirement that a medical device manufacturer's affirmations of fact must form the "basis of the bargain" in order for a plaintiff to succeed on her breach of express warranty claim. *See* 13 Pa. Con. Stat. § 2313(a)(1). And as discussed above, Ebert cannot make that showing.

Even if Ebert was correct and she could rely on statements that Dr. Ringold made to her to establish a breach of warranty claim, the record does not provide such evidence. Ebert testified that Dr. Ringold told her about "migration, bleeding risk, that's about it," and that the G2 filter was the "Cadillac of filters." (Ebert Dep. 220:25–221:2; 224:22–24.) She cannot show, however, that Dr. Ringold informed her that most instances of filter fracture "have been reported without any adverse clinical sequelae"—which is the warranty language upon which Ebert bases her claim. (G2 IFU 4.) Moreover, as stated previously, Dr. Ringold never read the G2 filter's IFU in its entirety, let alone before Ebert's procedure. (Ringold Dep. 23:25–24:7.)

D

Ebert next asserts a negligent misrepresentation claim. Bard argues that there is no record evidence showing that it made any misrepresentation, or that Dr. Ringold justifiably relied on any such misrepresentation. (Defs.' Mot. 14–15.)

Pennsylvania law requires a plaintiff to establish the following four elements to prove negligent misrepresentation: "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bortz v. Noon*, 729 A.2d 555, 561 (Pa. 1999). Negligent misrepresentation differs from intentional misrepresentation "in that the misrepresentation must concern a material fact and the speaker need not know his or her words are untrue, but must have failed to make a reasonable investigation of the truth of these words." *Id.* Like any action in negligence, "there must be an existence of a duty" owed by the defendant to the injured plaintiff. *Id.*

To establish the first element of her claim—*i.e.*, that Bard made a misrepresentation of material fact—Ebert relies on two Bard documents: the September 2005 U.S. Sales Training Manual and the G2 filter's IFU. The Sales Training Manual contains a section called "Features and Benefits," which touts the G2 filter as having "increased migration resistance," "reduced tilt" and "increased fracture resistance." (G2 Training Manual 30, Ex. W, ECF No. 138-23.) Ebert points out, however, that the G2 filter actually had higher failure rates as compared to other Bard and non-Bard filters. *See, e.g.*, (Freeman Aff. 5, 39–50; Ex. Q, ECF No. 133-17).

Even if the Sales Training Manual misrepresented the G2's heightened risks, there is nothing in the record showing that she or Dr. Ringold justifiably relied on those misrepresentations. There is no evidence that Dr. Ringold was aware of the manual's existence or contents. At oral argument, Ebert's counsel conceded that Dr. Ringold never saw or relied on any misstatements in the Sales Training Manual. (Apr. 27, 2020 Hr'g Tr. 97:13–17.) Dr. Ringold also did not believe that the Bard representative who visited his practice misrepresented any information concerning the G2 filter, nor does Ebert dispute that fact. (Defs.' SOF ¶ 34; Ringold Dep. 86:10–24).

Ebert also cites the G2 filter's IFU as evidence of a material misrepresentation of fact. (Pl.'s Resp. 21.) She points specifically to language in the IFU stating that "[m]ost cases of filter fracture, however, have been reported without any adverse clinical sequalae." (G2 IFU 4.) According to Ebert, this language indicated to Dr. Ringold that "there is an insignificant risk of sequalae associated with filter fractures," and had he been told the G2 filter presented a significant risk of fracture, he would not have used it. (Pl.'s Resp. 21.) Ebert cannot rely on the G2 filter's IFU for her negligent misrepresentation claim. First, she cites no evidence showing that most filter fractures resulted in adverse clinical sequalae. Second, as mentioned previously, Dr. Ringold did not read the G2 filter's IFU in its entirety, or rely on any statements in it. (Defs.' SOF ¶ 35; Ringold Dep. 23:25–24:7.)

E

Ebert's final cause of action relies upon the theory of strict liability. The parties contest whether Pennsylvania law even recognizes strict liability claims against prescription medical device manufacturers such as Bard. *See* (Defs.' Mot. 15–17; Pl.'s

Resp. 21–23). The Pennsylvania Supreme Court has yet to say whether such claims are cognizable. In the absence of a ruling from Pennsylvania's highest court, the Court must predict whether the Pennsylvania Supreme Court would recognize a strict liability claim against Bard for its G2 filter. *See Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 45–46 (3d Cir. 2009). In doing so, the Court must consider "relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand." *Id.* at 46 (quoting *Nationwide Mut. Ins. Co. v. Buffetta.*, 230 F.3d 634, 637 (3d Cir. 2000)). From a review of the available sources, the Court predicts that the Pennsylvania Supreme Court would bar a strict liability cause of action against Bard for its G2 filter. This prediction is limited to the facts of this case and the individual characteristics of IVC filters.

Pennsylvania law presumes that products can be the subject of strict liability tort actions. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 386 (Pa. 2014) (citing Restatement (Second) of Torts § 402A cmt. b). In 1996, however, the Pennsylvania Supreme Court adopted comment k of the Restatement (Second) of Torts § 402A to bar strict liability claims against manufacturers of prescription drugs. *Hahn v. Richter*, 673 A.2d 888, 890 (Pa. 1996). Comment k exempts "unavoidably unsafe products" that are "quite incapable of being made safe for their intended or ordinary use"—namely prescription drugs—from strict liability claims. Restatement (Second) of Torts § 402A cmt. k.

Bard asks the Court to predict that the Pennsylvania Supreme Court would apply comment k and *Hahn* to its G2 filter, thereby shielding it from a strict liability

claim. (Defs.' Mot. 15–17; Defs.' Reply 8–9.) In doing so, Bard cites several district court opinions from the Third Circuit predicting that the Pennsylvania Supreme Court would do just that. (Defs.' Mot. 15 n.1; Defs.' Reply 8 n.3.) Many of those decisions rely on the 2006 Pennsylvania Superior Court decision *Creazzo v. Medtronic, Inc.*, which extended *Hahn*'s holding to bar strict liability claims against prescription medical device manufacturers. 903 A.2d 24 (Pa. Super. Ct. 2006). In doing so, the *Creazzo* court explained that it could "find no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *Id.* at 32. The Court gives little persuasive weight to *Creazzo*; it is supported by scant reasoning and in the fourteen years since *Creazzo*, the Pennsylvania Supreme Court has not relied on it.[8]

More recently, the Pennsylvania Supreme Court has issued two opinions cautioning against "altering the common law of products liability," in both "general terms and with specific reference to *Hahn* and comment k." *Gross v. Coloplast Corp.*, 2020 WL 264691, at *3 (E.D. Pa. Jan. 17, 2020). These cases, taken together, undermine *Creazzo*'s persuasive force and suggest that the Pennsylvania Supreme Court would not apply comment k to categorically exempt all prescription medical devices from strict liability claims. The first case, *Tincher v. Omega Flex, Inc.*, cautions courts against creating such categorical exemptions: "Courts, which address evidence and arguments in individual cases, are neither positioned, nor resourced, to make the kind of policy judgments required to arrive at an *a priori* decision as to which

[8] *Creazzo* has been cited by the Pennsylvania Supreme Court once in a footnote on a spoliation issue. *See Pyertiz v. Commonwealth*, 32 A.3d 687, 692 n.5 (Pa. 2011).

There are two cases currently on appeal before the Pennsylvania Superior Court that raise the question of whether comment k should apply to prescription medical devices. *See Ebaugh v. Ethicon, Inc.*, No. 463 EDA 2018 (Pa Super. Ct.); *Emmet v. Ethicon, Inc.*, No. 1078 EDA 2019 (Pa. Super. Ct.).

individual products, or categories and types of products, should be exempt." 104 A.3d 328, 396 (Pa. 2014). Rather, Pennsylvania's highest court counsels that decisionmaking should be made in the presence of a rich factual record to allow for "a comprehensive discussion of the competing policies . . . which would support an informed, legislative-type judgment." *Lance v. Wyeth*, 85 A.3d 434, 454 (Pa. 2014).

This second case, *Lance*, more specifically cautions courts against expanding the reach of *Hahn* and comment k. The *Lance* court reaffirmed the decision in *Hahn*—i.e., categorically applying comment k to prescription drug manufacturers—but not without criticism. *See id.* at 438, 452 n.21. Indeed, the court admitted that *Hahn* "applied a rather one-dimensional analysis in its adoption of a *blanket* approach to comment k" and that its "truncated analysis . . . offers a poor foundation for extrapolation." *Id.* at 452 n.21 (emphasis added). The court further noted that "the terse opinion in *Hahn* does not so much as mention, let alone evaluate, the reasons why many other jurisdictions had interpreted comment k to require a case-by-case assessment concerning the availability of its protections." *Id.* (comparing *Hahn*, 673 A.2d at 889–91, with *Toner v. Lederle Labs.*, 732 P.2d 297, 304–09 (Idaho 1987)).

The cautionary language of *Tincher* and *Lance* leads the Court to predict that the Pennsylvania Supreme Court would not categorically extend *Hahn* and comment k to all prescription medical device manufacturers.[9] Rather, the Court predicts that Pennsylvania's highest court would instead analyze comment k's applicability to

[9] Recent district court opinions in the Third Circuit have also predicted this result. *See, e.g.*, *Moultrie v. Coloplast Corp.*, 2020 WL 1249354 (W.D. Pa. Mar. 16, 2020); *Gross v. Coloplast Corp.*, 2020 WL 264691 (E.D. Pa. Jan. 17, 2020); *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448 (W.D. Pa. 2019). *But see Kohn v. Ethicon, Inc.*, 2020 WL 733126 (E.D. Pa. Feb. 12, 2020); *Crockett v. Luitpold Pharms., Inc.*, 2020 WL 433367 (E.D. Pa. Jan. 28, 2020).

prescription medical devices on a case-by-case basis, determined largely by each case's developed factual record and the individual characteristics of the medical device at issue.

Here, the Court has the benefit of a fully developed factual record. Based on the evidence, the Court concludes that the Bard G2 filter is an "unavoidably unsafe product," such that the Pennsylvania Supreme Court would apply comment k to the filter, thereby shielding Bard from a strict liability claim. Indeed, every IVC filter, including Bard's G2 filter, carries risks of fracture, migration and perforation. *See* (IVC Article 4; Resnic Article 2, Ex. Z, ECF No. 157-4 (explaining that "it is impossible to design an implantable medical device with zero risk of failure")). A 2003 article reported, for example, that the rate of filter fracture in all IVC filters ranged from two to ten percent. (IVC Article 4.) Like all IVC filters, the G2 filter was no different, as it too carried risks of failure making it an "unavoidably unsafe product." *See* (Defs.' SOF ¶¶ 20–21). The Court accordingly grants summary judgment to Bard on the strict liability claim.

An appropriate Order follows.

BY THE COURT:

***/s/ Gerald J. Pappert***
GERALD J. PAPPERT, J.